

## REMARKS

Applicant respectfully requests reconsideration of the application in view of the foregoing amendments and the reasons that follow.

Claims 1 and 56 are amended to correct clerical errors, claim 61-65 are re-written in independent form, and claim 66 is added to recite a specific embodiment, e.g., where the physiologically active agent comprises an oestrogen. These amendments do not introduce new matter and do not require a further search. Moreover, they are believed to place the application in condition for allowance or, at the very least, in better condition for appeal. Applicant therefore requests entry of these amendments after final.

Applicant notes with appreciation the indication that claims 61-65 are allowable. Applicant has re-written these claims in independent form, as suggested in the Action. Applicant believes that new independent claim 66 is likewise allowable.

The sole remaining issue is the §103 rejection of claims 36-44 and 46-60 over Sunshine in view of Knight. Applicant respectfully traverses this rejection.

Sunshine is alleged to teach a topical, ibuprofen-containing composition that also may comprise ethanol and that can be combined with sun-protective agents, such as sunscreens that contain PABA ester. Knight is alleged to teach a shielded aerosol medicament dispenser. This combination of references fails to teach or suggest the present invention for at least the reasons detailed below.

As recited in the instant claims, the apparatuses of the present invention include a container that holds a non-occlusive percutaneous or non-occlusive transdermal drug delivery system, itself comprising a therapeutically effective amount of at least one physiologically active agent or prodrug, at least one dermal penetration enhancer, and at least one volatile liquid. As recited in the claims, “after application of the system to an area of the dermal surface or mucosal membrane, the area becomes touch-dry within three minutes of application.” There is no suggestion in the cited references of an apparatus containing such a composition.

Although Sunshine is alleged to teach a composition according to the invention, there is no teaching or suggestion in Sunshine of a composition formulated such that, after application to a dermal surface or mucosal membrane, the area becomes touch-dry within three minutes of application. The Examiner's refusal to give weight to this claim language is improper. Contrary to the assertion at page 5 of the Action, Sunshine does not teach a composition that is "the same as what is claimed." To the contrary, Sunshine indicates that the sunscreen-based compositions should comprise at least 50% water, in order to satisfy cited FDA guidelines. *See* Sunshine, column 9, lines 18-26. The Office Action does not address these teachings in Sunshine, which demonstrate that the Sunshine compositions would not become touch-dry within three minutes of application.

Applicant again directs the Examiner's attention to the Rule 132 Declaration of Timothy Morgan (a named inventor) submitted with the previous response. As explained previously, this Declaration evidences that a composition comprising a 50% aqueous ethanol vehicle (e.g., a vehicle comprising 50% water and 50% ethanol) does not become touch dry within three minutes of application. In view of this evidence, it is apparent that the sunscreen-based compositions suggested by Sunshine, comprising at least 50% water, would not read on the instant claims.

The Examiner refused to give weight to this Declaration because it references EP 522 405, which is directed to "Composite Ophthalmic Lenses." The Examiner will appreciate that the reference to EP 522 405 was a typographical error, and that EP 552 405 (copy attached) was intended. This is readily verified by a comparison of the examples reported in EP 552 405 to the examples discussed in the Declaration. Applicant respectfully urges the Examiner to again consider the Declaration (in view of EP 552 405), and its showing that compositions such as those suggested by Sunshine do not read on the instant claims.

Claims 42-44 and 56-60 are further distinguished from the cited references. These claims recite apparatuses for applying a metered dose, that comprise a metered dose applicator. Although the Office Action asserts that the aerosol dispenser of Knight "delivers a metered dose," this is simply not true.

As explained previously, the term “metered dose” as used in the art refers to a predetermined, measured amount, and a “metered dose applicator” is an applicator that delivers a predetermined, measured amount. There is no teaching or suggestion in Knight of a method of applying a metered dose, let alone of a metered dose applicator. Indeed, the focus of Knight appears to be to provide “a spray unit which will allow a medicament to be applied to any part of the body . . . neatly in a confined area.”

Although the Final Office Action did not address this point, the previous Office Action alleged that, “when the pumps of the aerosol and non-aerosol devices are depressed, the device delivers a metered dose of the composition.” As pointed out in Applicant’s previous response, that allegation is not supported by any evidence of record. To the contrary, because Knight does not teach or suggest that its dispenser provides a metered dose, those skilled in the art will expect that the dose dispensed by Knight’s dispenser will vary with the manner in which the device is depressed, *e.g.*, will vary with the magnitude and duration of the depressive force. That Knight’s dispenser does not deliver a metered dose is further reflected in its teaching that the hood protects the user’s clothing from overspray. *See, e.g.*, ’252 patent, column 4, lines 55-59 (“Any overspray in the form of mist or the like created by the unit will be confined within the hood.”). A device that is subject to overspray would not be a metered dose applicator.

Thus, Knight does not suggest the device recited in claims 42-44 and 56-60.

### **Conclusion**

Applicant believes that the present application is in condition for allowance, and an early notice to that effect is earnestly solicited. Should there be any questions regarding this submission, or should any issue remain, the Examiner is invited to contact the undersigned by telephone in order to advance prosecution.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated,

otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 CFR § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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